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No CBI 8892-6010587 8FHQ-92-12378 October 15, 1992

Document Processing Center (TS-790)
Office of Pollution Prevention and Toxics
Environmental Protection Agency
401 M Street., S.W.
Washington, D.C. 20460
Attn: Section 8(e) Coordinator (CAP Agreement)

Dear Coordinator:

### 8ECAP-0025

On behalf of the Regulatee and pursuant to Unit II B.1.b. and Unit II C of the 6/28/91CAP Agreement, E.1. Du Pont de Nemours and Co. hereby submits (in triplicate) the attached studies. Submission of this information is voluntary and is occasioned by unilateral changes in EPA's standard as to what EPA now considers as reportable information. Regulatee's submission of information is made solely in response to the new EPA §8(e) reporting standards and is not an admission: (1) of TSCA violation or liability; (2) that Regulatee's activities with the study compounds reasonably support a conclusion of substantial health or environmental risk or (3) that the studies themselves reasonably support a conclusion of substantial health or environmental risk.

The "Reporting Guide" creates new TSCA 8(e) reporting criteria which were not previously announced by EPA in its 1978 Statement of Interpretation and Enforcement Policy, 43 Fed Reg 11110 (March 16, 1978). The "Reporting Guide states criteria which expands upon and conflicts with the 1978 Statement of Interpretation. Absent amendment of the Statement of Interpretation, the informal issuance of the "Reporting Guide" raises significant due processes issues and clouds the appropriate reporting standard by which regulated persons can assure TSCA Section 8(e) compliance.

For Regulatee

Mark H. Christman

Counsel

Legal D-7158

1007 Market Street

Wilmington, DE 19898

(302) 774-6443

3/9/95

# **ATTACHMENT 1**

Submission of information is made under the 6/28/91 CAP Agreement, Unit II. This submission is made voluntarily and is occasioned by recent changes in EPA's TSCA §8(e) reporting standard; such changes made, for the first time in 1991 and 1992 without prior notice and in violation of Regulatee's constitutional due process rights. Regulatee's submission of information under this changed standard is not a waiver of its due process rights; an admission of TSCA violation or liability, or an admission that Regulatee's activities with the study compounds reasonably support a conclusion of substantial risk to health or to the environment. Regulatee has historically relied in good faith upon the 1978 Statement of Interpretation and Enforcement Policy criteria for determining whether study information is reportable under TSCA §8(e), 43 Fed Reg 11110 (March 16, 1978). EPA has not, to date, amended this Statement of Interpretation.

After CAP registration, EPA provided the Regulatee the June 1, 1991 "TSCA Section 8(e) Reporting Guide". This "Guide" has been further amended by EPA, EPA letter, April 10, 1992. EPA has not indicated that the "Reporting Guide" or the April 1992 amendment supersedes the 1978 Statement of Interpretation. The "Reporting Guide" and April 1992 amendment substantively lowers the Statement of Interpretation 's TSCA §8(e) reporting standard<sup>2</sup>. This is particularly troublesome as the "Reporting Guide" states criteria, applied retroactively, which expands upon and conflicts with the Statement of Interpretation.<sup>3</sup> Absent amendment of the Statement of Interpretation, the informal issuance of the "Reporting Guide" and the April 1992 amendment clouds the appropriate standard by which regulated persons must assess information for purposes of TSCA §8(e).

<sup>&</sup>lt;sup>2</sup>In sharp contrast to the Agency's 1977 and 1978 actions to soliciting public comment on the proposed and final §8(e) Policy, EPA has unilaterally pronounced §8(e) substantive reporting criteria in the 1991 Section 8(e) Guide without public notice and comment, See 42 Fed Reg 45362 (9/9/77), "Notification of Substantial Risk under Section 8(e): Proposed Guidance".

<sup>&</sup>lt;sup>3</sup>A comparison of the 1978 Statement of Interpretation and the 1992 "Reporting Guide" is a appended.

Throughout the CAP, EPA has mischaracterized the 1991 guidance as reflecting "longstanding" EPA policy concerning the standards by which toxicity information should be reviewed for purposes of §8(e) compliance. Regulatee recognizes that experience with the 1978 Statement of Interpretation may cause a review of its criteri. Regulatee supports and has no objection to the Agency's amending reporting criteria provided that such amendment is not applied to the regulated community in an unfair way. However, with the unilateral announcement of the CAP under the auspices of an OCM enforcement proceeding, EPA has wrought a terrific unfairness since much of the criteria EPA has espoused in the June 1991 Reporting Guide and in the Agency's April 2, 1992 amendment is new criteria which does not exist in the 1978 Statement of Interpretation and Enforcement Policy.

The following examples of new criteria contained in the "Reporting Guide" that is not contained in the <u>Statement of Interpretation</u> follow:

- o even though EPA expressly disclaims each "status report" as being preliminary evaluations that should <u>not</u> be regarded as final EPA policy or intent<sup>4</sup>, the "Reporting Guide" gives the "status reports" great weight as "sound and adequate basis" from which to determine mandatory reporting obligations. ("Guide" at page 20).
- o the "Reporting Guide" contains a matrix that establishes new numerical reporting "cutoff" concentrations for acute lethality information ("Guide" at p. 31). Neither this matrix nor the cutoff values therein are contained in the <u>Statement of Interpretation</u>. The regulated community was not made aware of these cutoff values prior to issuance of the "Reporting Guide" in June, 1991.
- othe "Reporting Guide" states new specific definitional criteria with which the Agency, for the first time, defines as 'distinguishable neurotoxicological effects'; such criteria/guidance not expressed in the 1978 Statement of Interpretation.<sup>5</sup>;
- othe "Reporting Guide" provides new review/ reporting criteria for irritation and sensitization studies; such criteria not previously found in the 1978 <u>Statement of Interpretation/Enforcement Policy</u>.
- othe "Reporting Guide" publicizes certain EPA Q/A criteria issued to the Monsanto Co. in 1989 which are not in the <u>Statement of Interpretation</u>; have never been published in the <u>Federal Register</u> or distributed by the EPA to the Regulatee. Such Q/A establishes new reporting criteria not previously found in the 1978 <u>Statement of Interpretation/Enforcement Policy</u>.

The 'status reports' address the significance, if any, of particular information reported to the Agency, rather than stating EPA's interpretation of §8(e) reporting criteria. In the infrequent instances in which the status reports contain discussion of reportability, the analysis is invariably quite limited, without substantial supporting scientific or legal rationale.

See, e.g. 10/2/91 letter from Du Pont to EPA regarding the definition of 'serious and prolonged effects' as this term may relate to transient anesthetic effects observed at lethal levels; 10/1/91 letter from the American Petroleum Institute to EPA regarding clarification of the Reporting Guide criteria.

In discharging its responsibilities, an administrative agency must give the regulated community fair and adequate warning to as what constitutes noncompliance for which penalties may be assessed.

Among the myriad applications of the due process clause is the fundamental principle that statutes and regulations which purport to govern conduct must give an adequate warning of what they command or forbid.... Even a regulation which governs purely economic or commercial activities, if its violation can engender penalties, must be so framed as to provide a constitutionally adequate warning to those whose activities are governed.

Diebold, Inc. v. Marshall, 585 F.2d 1327, 1335-36 (D.C. Cir. 1978). See also, Rollins Environemntal Services (NJ) Inc. v. U.S. Environmental Protection Agency, 937 F. 2d 649 (D.C. Cir. 1991).

While neither the are rules, This principle has been applied to hold that agency 'clarification', such as the <u>Statement of Interpretation</u>, the "Reporting Guide" nor the April 1992 amendments will not applied retroactively.

...a federal court will not retroactively apply an unforeseeable interpretation of an administrative regulation to the detriment of a regulated party on the theory that the post hoc interpretation asserted by the Agency is generally consistent with the policies underlying the Agency's regulatory program, when the semantic meaning of the regulations, as previously drafted and construed by the appropriate agency, does not support the interpretation which that agency urges upon the court.

Standard Oil Co. v. Federal Energy Administration, 453 F. Supp. 203, 240 (N.D. Ohio 1978), aff'd sub nom. Standard Oil Co. v. Department of Energy, 596 F.2d 1029 (Em. App. 1978):

The 1978 Statement of Interpretation does not provide adequate notice of, and indeed conflicts with, the Agency's current position at §8(e) requires reporting of all 'positive' toxicological findings without regard to an assessment of their relevance to human health. In accordance with the statute, EPA's 1978 Statement of Interpretation requires the regulated community to use scientific judgment to evaluate the significance of toxicological findings and to determining whether they reasonably support a conclusion of a substantial risk. Part V of the Statement of Interpretation urges persons to consider "the fact or probability" of an effect's occurrence. Similarly, the 1978 Statement of Interpretation stresses that an animal study is reportable only when "it contains reliable evidence ascribing the effect to the chemical." 43 Fed Reg. at 11112. Moreover, EPA's Statement of Interpretation defines the substantiality of risk as a function of both the seriousness of the effect and the probability of its occurrence. 43 Fed Reg 11110 (1978). Earlier Agency interpretation also emphasized the "substantial" nature of a §8(e) determination. See 42 Fed Reg 45362, 45363

(1977). [Section 8(e) findings require "extraordinary exposure to a chemical substance...which critically imperil human health or the environment"].

The recently issued "Reporting Guide" and April 1992 Amendment guidance requires reporting beyond and inconsistent with that required by the <u>Statement of Interpretation</u>. Given the statute and the <u>Statement of Interpretation</u>'s explicit focus on substantial human or environmental risk, whether a substance poses a "substantial risk" of injury requires the application of scientific judgment to the available data on a case-by-case basis.

If an overall weight-of-evidence analysis indicates that this classification is unwarranted, reporting should be unnecessary under §8(e) because the available data will not "reasonably support the conclusion" that the chemical presents a <u>substantial</u> risk of serious adverse consequences to human health.

Neither the legislative history of §8(e) nor the plain meaning of the statute support EPA's recent lowering of the reporting threshold that TSCA §8(e) was intended to be a sweeping information gathering mechanism. In introducing the new version of the toxic substances legislation, Representative Eckhart included for the record discussion of the specific changes from the version of H. R. 10318 reported by the Consumer Protection and Finance Subcommittee in December 1975. One of these changes was to modify the standard for reporting under §8(e). The standard in the House version was changed from "causes or contributes to an unreasonable risk" to "causes or significantly contributes to a substantial risk". This particular change was one of several made in TSCA §8 to avoid placing an undue burden on the regulated community. The final changes to focus the scope of Section 8(e) were made in the version reported by the Conference Committee.

The word "substantial" means "considerable in importance, value, degree, amount or extent". Therefore, as generally understood, a "substantial risk" is one which will affect a considerable number of people or portion of the environment, will cause serious injury and is based on reasonably sound scientific analysis or data. Support for the interpretation can be found in a similar provision in the Consumer Product Safety Act. Section 15 of the CPSA defines a "substantial product hazard" to be:

"a product defect which because of the pattern of defect, the number of defective products distributed in commerce, the severity of the risk, or otherwise, creates a substantial risk of injury to the public." Similarly, EPA has interpreted the word 'substantial' as a quantitative measurement. Thus, a 'substantial risk' is a risk that can be quantified, See, 56 Fed Reg 32292, 32297 (7/15/91). Finally, since information pertinent to the exposure of humans or the environment to chemical substances or mixtures may be obtained by EPA through Sections 8(a) and 8(d) regardless of the degree of potential risk, §8(e) has specialized function. Consequently, information subject to §8(e) reporting should be of a type which would lead a reasonable man to conclude that some type action was required immediately to prevent injury to health or the environment.

# Attachment

# Comparison:

Reporting triggers found in the 1978 "Statement of Interpretation/ Enforcement Policy", 43 Fed Reg 11110 (3/16/78) and the June 1991 Section 8(e) Guide.

	8 POLICY ITERIA EXIST?	New 1991 GUIDE CRITERIA EXIST?
ACUTE LETHALITY		
Oral Dermal Inhalation (Vapors) aerosol dusts/ particles	N} N} } <sup>6</sup> N} N}	Y} Y} Y} Y}
SKIN IRRITATION	N	Y <sup>8</sup>
SKIN SENSITIZATION (ANIMALS)	N	Y <sup>9</sup>
EYE IRRITATION	N	Y <sup>10</sup>
SUBCHRONIC (ORAL/DERMAL/INHALATION)	N	Y <sup>11</sup>
REPRODUCTION STUDY	N	Y <sup>12</sup>
DEVELOPMENTAL TOX	Y <sup>13</sup>	Y <sup>14</sup>

<sup>643</sup> Fed Reg at 11114, comment 14:

"This policy statements directs the reporiting of specifiec effects when unknown to the Administrator. Many routine tests are based on a knowledge of toxicity associated with a chemicalL unknown effects occurring during such a range test may have to be reported if they are those of concern tot he Agency and if the information meets the criteria set forth in Parts V and VII."

<sup>&</sup>lt;sup>7</sup>Guide at pp.22, 29-31.

<sup>8</sup>Guide at pp-34-36.

<sup>&</sup>lt;sup>9</sup>Guide at pp-34-36. <sup>10</sup>Guide at pp-34-36.

<sup>&</sup>lt;sup>11</sup>Guide at pp-22; 36-37.

<sup>&</sup>lt;sup>12</sup>Guide at pp-22

<sup>1343</sup> Fed Reg at 11112

<sup>&</sup>quot;Birth Defects" listed.

<sup>14</sup>Guide at pp-22

NEUROTOXICITY	N	Y <sup>15</sup>
CARCINOGENICITY	Y <sup>16</sup>	Y <sup>17</sup>
MUTAGENICITY		
In Vitro	Y} <sup>18</sup>	Y} <sup>19</sup>
In Vivo	<b>Y</b> }	<b>Y</b> }
ENVIRONMENTAL		
Bioaccumulation	<b>Y</b> }	N
Bioconcentration	Y} <sup>20</sup>	N
Oct/water Part. Coeff.	Y}	N
Acute Fish	N	N
Acute Daphnia	N	N
Subchronic Fish	N	N
Subchronic Daphnia	N	N
Chronic Fish	N	N
AVIAN		
Acute	N	N
Reproductive	N	N N
Reprodcutive	N	N N

<sup>15 &</sup>lt;u>Guide</u> at pp-23; 33-34. 1643 <u>Fed Reg</u> at 11112

<sup>&</sup>quot;Cancer" listed

<sup>&</sup>lt;sup>17</sup>Guide at pp-21.

<sup>1843</sup> Fed Reg at 11112; 11115 at Comment 15

"Mutagenicity" listed/ in vivo vs invitro discussed; discussion of "Ames test".

<sup>&</sup>lt;sup>19</sup>Guide at pp-23.
<sup>20</sup>43 Fed Reg at 11112; 11115 at Comment 16.

CAS# 336-07-2 , alpha, alpha, onega, -

Chem: 1H,6H-dodecafluorohexane;  $\alpha,\alpha,\omega$ -trihydrooctafluoro-

amyl chloride;  $\alpha,\alpha,\omega$ —trihydrooctafluoroamyl bromide; 1H,3-chlorohexafluoropropane; 1H,3H-hexafluoro-

propane

Title: Screening test for anesthetic properties

Date: 2/25/60

Summary of Effects: Convulsions

C. W. Maynerd K. T. Dishart Medical Research Project MR-485-/ E. I. du Pont de N vours & Co. Haskell Laboratory for Toxicology and Industrial Medicine Haskell Laboratory Report No. 22-60

21.5

Materials rested:	Materials Tested: 1H, bH-Dodecafluorobexane Κ, W-Trihydrooctafluoroemyl chloride	Haskell Nos.: 2403
	α, α, ω-Trihydrooctafluorosmyl bromide	<b>240</b> 5
	18, 2-Chlorohexafluoropropane 18, 78-Rexafluoromana	505
		long.
Submitted by:	K. T. Dishart, Organic Chemicals Department	Other Codes: DV-8684, DV-8685
	Fluorochemicals Development Div.	DV-8686, DV-3687
		DV-8688

Screening Test for Anesthetic Properties

Mice were exposed, two at a time, to each of a series of graded concentrations of the test chemical in a 3.86 liter injection of the test chemical, rotation of the jar was begun. The criterion of anesthesia was inability of the Concentrations were computed as per cent by volume of the jar and the required volume of liquid was injected through a rubber serum vial cap in the jar lid. As soon as possible after mouse to maintain an upright position for a minimum of 15 consecutive seconds. Mice were observed for clinical signs of toxicity for at least .0 days after exposure. dar, adapted for rotation at 14 rpm. Method:

1H,6H-Dodecafluorohexane B.P. 93°C Predicted AD50 0.5-1.06\* Haskell No. 2403 DV-8684

Mice admitted to jar after vaporization to prevent mice from contacting liquid.  During exposure: Violent convulsions throughout.  Post exposure: Severely labored breathing. Recovery 12 - 2001.	Mice admitted to jar after vaporization.  During exposure: Intermittent convulsions, initially; then minimal activity; severely labored breathing.  Post exposure: Labored breathing continued. Recovered in about 1/2 hr.	No signs of anesthesia or toxicity.
2:45	\$:00	10:00
0:45 0:45		
+	1	•
5	a	1

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Observations	coctafluoroamyl chloride B.P. 106°C Predicted ADen 0.26*	During exposure: Severe, continual convulsions and labored breathing.  Post exposure: Labored breathing continued; hyperresponsive to noise for 7 min.  Recovery shortly thereafter	During exposure: Both contacted liquid. Convulsions and rollover 20 to 35 sec.; minimal activity thereafter. Post exposure: Hyperresponsive to noise; rapid, shallow breathing. Recovery in 3 minutes.	DW-8686 &, X, W-Iribydrooctaflucroamyl bromide B.P. 120°C Predicted ADSO 0.15*	During exposure: Intermittent convulsions and gusping; not relaxed.  Post exposure: Convulsions for & min.: recovery theresetter	During exposure: Struggling and convulsions throughout. Post exposure: One mouse, violent convulsions. Recovery in about h min.		During exposure: One mouse contacted liquid and diel at 2:00, after relaxed roll- over. Other mouse - relaxed from start of rollover. Post exposure: One survivor was unresponsive for 0:35. Inbored breathing for more than a min. then recovered	During exposure: Relaxed initially, then struggled; rapid and deep breathing. Post exposure: One responsive immediately, other at 0:15. Recovered by 1 min.	ן ר	During exposure: Apparent relaxation at 2:00; struggling from 2:15 until end of exposure; labored breathing. Post exposure: Labored breathing; recovered in min.	During exposure: One mouse seemed confused. Otherwise no signs of toxicity or anesthesis.	
Exposure Time (Min-sec)	, centribyd	00:9	5: 30	, W-friby	3:30	2:00	Chlorohexa	5:00	2:00	5:00	5:00	7:00	
Induction Time (Min-sec)	DV-8685 C, C, CLTribydrocet	80:¥	0:30 0:30	8686 A,X	1:09	2:50 2:50	DV-8687 1H, 3-	0:20 0:20	0:24 0:29	62:0 \$2:0	5†;0 0€;0		
Anesthesia (+ or -)	1017Z	+	+		+	+	2406	+	+	+	+		
Concentration (Vol 4)	Haskell No.	ሳ•0	0.2	Haskell No. 2405	1.0	4.0	Haskell No.	(cs) کر	17.5	15 (ca)	10	~	

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(Asprost from	Haskell No. 2407 DV-8688 1H, 39-Hexafluoropropane B.P. 10°C Predicted AD50 10-154*	During exposure: Relaxed for 9:00, then showed hind leg extension; rapid, sh low breathing noted occasionally. Post exposure: Unresponsive for 0:15. Recovered by 1 min.	During exposure: Relaxed for 5:00 then struggled and walked incomdinately.	During exposure: One mouse slightly incoordinate.  Post exposure: Slightly remid treathing several minutes.	No signs of toxicity or anesthesis.
Exposure Time (Min-sec)	H-Hexafluor	10:00	10:00	10:00	10:00
Time Time Time (Min-sec)	-8688 из.	0:45 0:45	0:50 1:00		
tration Anesthesia (Vol \$) (+ or -)	0. 2407 DV.	<b>.</b>	+	•	•
tration (Vol 4)	Haskell N	10.14	7.8	5.2	1.0

hal-

further testing as anesthetic agents. These three chemicals caused convulsions and severe respiratory impairment, On the basis of these tests, Haskell Nos. 2403, 2404, and 2405 (DV-8684, 8685, and 8686) are not recommended for but not a relaxed state of anesthesia, Comments:

Haskell Nos. 2406 and 2407 (DV-2687 and 3688) are recommended for further animal testing as anesthetic agents.

minimal and temporary effects on respiration. A concentration of 20% produced anesthesia with relaxation throughout exposure followed by rapid recovery. One mouse which unavoidably contacted the chemical as liquid prior to The lowest concentration of Haskell No. 2406 producing anesthesia was 10%. A concentration of 5% caused essen-Concentrations of 10, 15 and 17.5% induced anesthesia with intermittent relaration and only tially no effect. vaporization died.

The lowest concentration of Haskell No. 2407 producing anesthesia was 7.8%. Concentrations of 1 and 5 per cent did not produce anesthesia or marked signs of toxicity. A concentration of 7.8% induced anesthesia with initial relaxation, but mice struggled and valked prior to the end of the 10 minute exposure. 10.4% caused more rapid induction of amesthesis, but mice were observed to extend their bind legs prior to the end of the exporure. Only slight, transfent effects were observed on respiration at 10.4%.

\* Predicted on the basis of criteria established by K. Distart.

Reported by:

Approved by:

Date: February 25, 1960

EEH: ecd

# Triage of 8(e) Submissions

	Study type (circle appropriate):  Group 1 - Gordon Cash (1 copy total)  ECO AQUATO  Group 2 - Ernie Falke (1 copy total)  ATOX SBTOX SEN  Group 3 -HERD (1 copy each)  STOX CTOX EPI RTOX G  STOX/ONCO CTOX/ONCO IMMUNO CYTO N  Other (FATE, EXPO, MET, etc.):	
Group 1 - Gordon Cash (1 copy total)  ECO AQUATO  Group 2 - Emie Falke (1 copy total)  ATOX SBTOX SEN WINEUR  Group 3 -HERD (1 copy each)  STOX CTOX EPI RTOX GROUP STOX/ONCO CTOX/ONCO IMMUNO CYTO NE  Other (FATE, EXPO, MET, etc.):  Notes:  This is the original 8(e) submission; refile after triage evaluation.  This original submission has been split; rejoin after triage evaluation.  Other:	Group 1 - Gordon Cash (1 copy total)  ECO AQUATO  Group 2 - Ernie Falke (1 copy total)  ATOX SBTOX SEN WINEUR  Group 3 -HERD (1 copy each)  STOX CTOX EPI RTOX G  STOX/ONCO CTOX/ONCO IMMUNO CYTO N  Other (FATE, EXPO, MET, etc.):	
Group 2 - Ernie Falke (1 copy total)  ATOX SBTOX SEN  WINEUR  Group 3 -HERD (1 copy each)  STOX CTOX EPI RTOX GOVERNOUS STOX/ONCO CTOX/ONCO IMMUNO CYTO NE  Other (FATE, EXPO, MET, etc.):  Notes:  This is the original 8(e) submission; refile after triage evaluation.  This original submission has been split; rejoin after triage evaluation.  Other:	Group 2 - Ernie Falke (1 copy total)  ATOX SBTOX SEN  Group 3 -HERD (1 copy each)  STOX CTOX EPI RTOX G  STOX/ONCO CTOX/ONCO IMMUNO CYTO N  Other (FATE, EXPO, MET, etc.):	
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<u> </u>	Initials: <u>J</u> W Date: # 6/21/96	

	WOLUNTARY ACTIONS:  MOD STUDIES PLANNEDAINED RWAY  MOD STUDIES PLANNEDAINED RWAY  MOD LARELASIDS CHANGES  MOD PROCESSALANDEING CHANGES  MOD APPAUSE DISCONTINUED  MOD PRODUCTION DISCONTINUED	Propent, 14, 34-Chloroheraflumo-	Property, 14,34 - hexafluero - Unknown	IMMUNO (ANIMAL)	USE: PRODUCTION:
CECATS/TRIAGE TRACKING DBASE ENTRY FORM	INFORMATION REQUESTED: FLWP DATE: 6501 NO INFO REQUESTED 6502 INFO REQUESTED (TECH) 6503 INFO REQUESTED (VOL ACTIONS) 6504 INFO REQUESTED (REPORTING RATIONALE) 6504 INFO REQUESTED (REPORTING RATIONALE) 6505 REFER TO CHEMICAL SCREENING 6605 CAP NOTICE	CASE 05 09 05 05 05 05 05 05 05 05 05 05 05 05 05	Unknown LEC	HUMAN EXPOS (PROD CONTAM)   01 02 04 0241	MUS LOW Acut Inhelation Toxicity MED HIGH
	CECATS DATA Submission # 8EHQ. 1092 - 12378 SEO.H  TYPE INT SUPP FLWP SUBMITTER NAME E. I. DUDONT AND COMPONY	SUB DATE: 10/15/93 OTS DATE: 10/37/93 CHEMICAL NAME:  CHEMICAL NAME:  CHEMICAL NAME:	11 11	AN) 01 02 04 (AL) (IN VITRO) 01 02 04 (TRO) 01 02 04	TRIAGR DATA NON-CRI INVENTORY ONGOING REVIEW YES YES (DROPREFER) NO NO (CONTINUE) (14 IT AMIN) REFT.R

### 12378A

# 1H,6H-Dodecafluorohexane

L

Acute inhalation toxicity is of low concern based on no deaths (0/2) in mice exposed to 50000 ppm for 2.75 min, 20000 ppm for 5 min and 10000 ppm for 10 min. Clinical signs included convulsions and labored breathing (≥20000).

# $\alpha,\alpha,\omega$ -Trihydrooctafluoramyl chloride

L

Acute inhalation toxicity is of low concern based on no deaths (0/2) in mice exposed to 4000 ppm for 6 min, and 2000 ppm for 5.5 min. Clinical signs included convulsions, breathing abnormalities and hyperresponsive to noise.

# $\alpha,\alpha,\omega$ -Trihydrooctafluoramyl bromide

L

Acute inhalation toxicity is of low concern based on no deaths (0/2) in mice exposed to 10000 ppm for 3.5 min and 4000 ppm for 5 min. Clinical signs included convulsions (both doses), gasping (10000) and struggling (4000).

# 1H,3-Chlorohexafluoropropane

L

Acute inhalation toxicity is of low concern based on no deaths (0/2) in mice exposed to 175000, 150000 and 100000 ppm for 5 min, and 50000 ppm for 7 min. There was 1/2 deaths at exposure to 200000 ppm for 5 min. Clinical signs included struggling and labored breathing (≥100000) and unresponsive (high dose).

## 1H,3H-Hexafluoropropane

L

Acute inhalation toxicity is of low concern based on no deaths (0/2) in mice exposed to 10000, 52000, 78000 and 104000 ppm for 10 min. Clinical signs included slight incoordination (52000, 78000), hind leg extension, breathing abnormalities and

unresponsiveness (high dose).